

CLAIMS

What is claimed is:

1. Oxcarbazepine Form B.
2. Oxcarbazepine having a PXRD diffraction pattern with peaks at about 11.9, 14.4, 20.0, 23.0, 25.1 ± 0.2 degrees two-theta.
3. The oxcarbazepine of claim 2 having a PXRD diffraction pattern with peaks at about 11.9, 14.4, 17.7, 19.4, 20.0, 21.1, 23.0, 24.0, 24.4, 25.1 , 26.0 ± 0.2 degrees two-theta.
4. The oxcarbazepine of claim 3 having a PXRD diffraction pattern substantially as depicted in figure 1.
5. A process for preparing oxcarbazepine Form B comprising the steps of:
 - a) preparing a solution of oxcarbazepine in a mixture of dichloromethane and toluene, and
 - b) evaporating the toluene and the dichloromethane leaving Form B as a residue.
6. The process of claim 5, wherein the solution is prepared by dissolving oxcarbazepine in dichloromethane and adding the dichloromethane to toluene.
7. The oxcarbazepine Form B prepared by the process of claim 5.
8. A process for preparing oxcarbazepine Form B comprising the steps of:
 - a) preparing a solution of oxcarbazepine in toluene;
 - b) heating the solution;

- c) cooling the solution at a rate of $60^{\circ}\text{C min}^{-1}$ or above to cause formation of a precipitate; and
 - d) separating the precipitate.
9. The process of claim 8, wherein the solution is heated to about reflux.
10. The process of claim 8, wherein the solution is cooled to a temperature of about 0°C .
11. The oxcarbazepine Form B prepared by the process of claim 8.
12. Oxcarbazepine Form C.
13. Oxcarbazepine characterized by PXRD peaks at about 11.7, 21.7, 23.2, 24.4 ± 0.2 degrees two-theta
14. The oxcarbazepine of claim 13 characterized by PXRD peaks at about 11.7, 17.0, 18.0, 21.7, 23.2, 24.4, 26.0 ± 0.2 degrees two-theta.
15. The oxcarbazepine of claim 14 characterized by a PXRD diffraction pattern substantially as depicted in figure 2.
16. A process for preparing oxcarbazepine Form C comprising the steps of:
- a) preparing a solution of oxcarbazepine in toluene;
 - b) heating the solution;
 - c) cooling the solution at a rate of from about 20 to $60^{\circ}\text{C min}^{-1}$ to cause formation of a precipitate; and
 - d) separating the precipitate.
17. The process of claim 16, wherein the solution is cooled at a rate of about 40°C

per minute.

18. The process of claim 16, wherein the solution is cooled to about 0°C.
19. The process of claim 16, wherein the solution is heated to about reflux.
20. The oxcarbazepine Form C prepared by the process of claim 16.
21. Oxcarbazepine Form D.
22. Oxcarbazepine characterized by PXRD peaks at about 11.7, 14.2, 24.3 ± 0.2 degrees two-theta.
23. The oxcarbazepine of claim 22 characterized by a PXRD diffraction pattern substantially as depicted in figure 3.
24. A process for preparing oxcarbazepine Form D comprising the steps of:
 - a) preparing a solution of oxcarbazepine in toluene; and
 - b) evaporating the toluene leaving a residue of oxcarbazepine Form D.
25. The process of claim 24, further comprising a step of heating the solution before evaporating.
26. The process of claim 25, wherein the solution is heated to about reflux.
27. The process of claim 25, further comprising cooling the heated solution before evaporating.
28. The process of claim 27, wherein the solution is cooled to about 0°C.

29. The process of claim **24**, further comprising a step of cooling the solution.
30. The process of claim **29**, wherein the solution is cooled to about 0°C.
31. The process of claim **24**, wherein the toluene is removed from the solution by evaporation.
32. The oxcarbazepine Form D prepared by the process of claim **24**.
33. An oxcarbazepine chloroform solvate.
34. Oxcarbazepine chloroform solvate Form E.
35. An oxcarbazepine chloroform solvate characterized by a PXRD pattern with peaks at about 14.5, 15.0, 18.2, 21.4, 22.9, 24.0, 25.8, 26.0 ± 0.2 degrees two-theta.
36. The oxcarbazepine solvate of claim **35** characterized by a PXRD diffraction pattern substantially as depicted in figure 4.
37. The oxcarbazepine chloroform solvate of claim **33** containing about a 27 weight % chloroform.
38. A process for preparing oxcarbazepine chloroform solvate comprising:
- a) causing formation of a precipitate from a solution of oxcarbazepine in chloroform, and
 - b) separating the precipitate.
39. The process of claim **38**, further comprising a step of heating the solution before causing formation of the precipitate.

40. The process of claim 39, further comprising a step of cooling the heated solution, whereby cooling causes formation of the precipitate.
41. The process of claim 39, wherein the solution is heated to an elevated temperature of from about 50°C to about 60°C.
42. The process of claim 41, wherein the solution is heated to an elevated temperature of about 55°C.
43. The process of claim 41, wherein the heated solution is cooled to a reduced temperature of from about 10°C to about 20°C.
44. The process of claim 43, wherein the reduced temperature is about 16°C.
45. The oxcarbazepine chloroform solvate produced by the process of claim 37.
46. A process for preparing oxcarbazepine Form A comprising:
- a) providing oxcarbazepine chloroform solvate Form E,
 - b) heating the oxcarbazepine chloroform solvate, and
 - c) recovering oxcarbazepine as Form A.
47. The process of claim 46, wherein the oxcarbazepine solvate Form E is heated to an elevated temperature in the range of from about 40°C to about 80°C.
48. The process of claim 47, wherein the elevated temperature is about 60°C.
49. A process for preparing oxcarbazepine Form A comprising
- a) providing oxcarbazepine Form B,
 - b) heating the oxcarbazepine, and

- c) recovering the oxcarbazepine as Form A.
50. The process of claim **49**, wherein oxcarbazepine Form B is heated to an elevated temperature in the range of from about 60°C to about 120°C.
51. The process of claim **50**, wherein the elevated temperature is about 60°C.
52. A process for the preparation of oxcarbazepine Form C comprising
- a) providing oxcarbazepine Form B,
 - b) maintaining the oxcarbazepine at a temperature in the range of from about 20 to about 30°C, and
 - c) recovering the oxcarbazepine as Form C.
53. A process for preparing oxcarbazepine Form A comprising:
- a) contacting oxcarbazepine selected from the group consisting of oxcarbazepine Form B, oxcarbazepine Form C and oxcarbazepine Form D with a protic solvent; and
 - b) recovering oxcarbazepine as Form A.
54. The process of claim **53**, wherein the forms of oxcarbazepine are suspended in the protic solvent.
55. The process of claim **53**, wherein the protic solvent is selected from the group consisting of water and ethanol.
56. The process of claim **54**, wherein the oxcarbazepine is suspended in the protic solvent from about two hours to about three days.
57. The process of claim **56**, wherein the oxcarbazepine is suspended for about one day.

58. A pharmaceutical composition comprising:
- a) oxcarbazepine selected from the group consisting of oxcarbazepine Form B, oxcarbazepine Form C, oxcarbazepine Form D and oxcarbazepine Form E; and
 - b) a pharmaceutically acceptable excipient.
59. The pharmaceutical composition of claim 58, wherein the composition is mixed with one or more forms of oxcarbazepine.
60. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 58.
61. The pharmaceutical dosage form of claim 60, wherein the dosage form is a capsule or tablet.
62. The pharmaceutical dosage form of claim 61, wherein the dosage form is a tablet.
63. The pharmaceutical dosage form of claim 60, containing a unit dosage of about 150mg to about 600mg oxcarbazepine.
64. The pharmaceutical dosage form of claim 63, containing a unit dosage selected from the group consisting of about 150mg, 300mg and 600mg.
65. The pharmaceutical dosage form of claim 60, wherein the dosage form is an oral suspension.
66. The pharmaceutical dosage form of claim 65, wherein the dosage is about 60mg ml⁻¹.

67. The pharmaceutical dosage form of claim 66, wherein the dosage is about 300mg ml⁻¹.
68. A method of preventing or reducing the severity of seizures comprising administering the pharmaceutical composition of claim 58.
69. The method of claim 68, wherein the seizures are associated with epilepsy.
70. A method of treating Parkinson's disease comprising administering the pharmaceutical composition of claim 58.
71. A method of depressing the central nervous system comprising administering the pharmaceutical composition of claim 58.
72. The method of claim 71, wherein the central nervous system is depressed by blocking voltage sensitive sodium channels.